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TO:

Commissioner for Patents

Attn: Jessica Lynn Sarcione

Patent Examining Corps

Facsimile Center P.O. Box 1450

Alexandria, VA 22313-1450

FAX NUMBER <u>571-273-2129</u>

* Please deliver to Examiner Jessica Lynn Sarcione in Art Unit 3766. *

Document(s) Transmitted: Proposed Claim Amendments

Total pages of this transmission, including cover letter: 4

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In re. Patent Application of: Steven D. Girouard et al.

Examiner: Jessica Reidel

Serial No.: <u>10/788,906</u>

Group Art Unit: 3766

FROM: Janet E. Embretson

OUR REF: 279.696US1

Filed: February 27, 2004

Docket No.: <u>279.696US1</u>

Title: METHOD AND APPARATUS FOR DEVICE CONTROLLED GENE EXPRESSION

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2/25/10 Date of Transmission

PATENT S/N 10/788,9<u>06</u>

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Steven D. Girouard et al. Applicant:

Examiner: Jessica Reidel

Serial No.:

10/788,906

Group Art Unit: 3766 Docket: 279.696US1

Customer No.: 45458

February 27, 2004

Confirmation No.: 4545

Title:

Filed:

METHOD AND APPARATUS FOR DEVICE CONTROLLED GENE

EXPRESSION

PROPOSED CLAIM AMENDMENTS

1. (Currently Amended) A system, comprising:

an implantable gene regulatory signal delivery device that emits, in response to a gene regulatory control signal, a regulatory signal which regulates transcription from a regulatable transcriptional control element;

an implantable cardiac rhythm management (CRM) device including:

a sensor to sense a physiological signal indicative of a predetermined cardiac condition;

an event detector configured to detect the predetermined cardiac condition from the sensed physiological signal and produce one or more condition parameters related to one of a type and a degree of the predetermined cardiac condition;

and

a controller coupled to the sensor and electrically connected to the gene regulatory signal delivery device, the controller configured to produce the gene regulatory control signal, transmit the gene regulatory signal to the gene regulatory signal delivery device to trigger an emission of the regulatory signal in response to a detection of the predetermined cardiac condition, and quantitatively control the emission of the regulatory signal based on the one or more condition parameters, wherein the controller is electrically wired to the gene regulatory signal delivery device; and

one or more implantable leads providing for electrical connections between the implantable gene regulatory signal delivery device and the implantable CRM device,

wherein the controller is electrically wired to the gene regulatory signal delivery device through the electrical connections, and

wherein the regulatory signal is selected to regulate the regulatable transcriptional control element in a vector having the regulatable transcriptional control element operably linked to an open reading frame, the expression of which treats the predetermined cardiac condition.

32. (Withdrawn-Currently Amended) A system, comprising:

an implantable gene regulatory signal delivery device that emits, in response to a gene regulatory control signal, a regulatory signal which regulates transcription from a regulatable transcriptional control element; and

an implantable medical device system including:

a sensor to sense a physiological signal indicative of a predetermined cardiac condition;

an event detector configured to detect the predetermined cardiac condition from the sensed physiological signal and produce one or more condition parameters related to at least one of a type and a degree of the predetermined cardiac condition;

an implant telemetry module to receive an external command; and

an implant controller coupled to the sensor and the implant telemetry module, the implant controller configured to quantitatively control the emission of the regulatory signal based on the one or more condition parameters and the external command, wherein the implant controller is electrically wired to the gene regulatory signal delivery device;

one or more implantable leads providing for electrical connections between the implantable gene regulatory signal delivery device and the implantable medical device.

one or more implantable leads providing for electrical connections
between the implantable gene regulatory signal delivery device and the
implantable medical device wherein the implant controller is electrically wired to
the gene regulatory signal delivery device through the electrical connections; and

an external system including:

an external telemetry module to transmit the external command to the implant telemetry module;

a user input device adapted to receive the external command; and an external controller adapted to automatically analyze signals acquired by the implantable medical device and generate the external command when deemed necessary as a result of the analysis,

wherein the regulatory signal is selected to regulate a regulatable transcriptional control element in a vector having the regulatable transcriptional control element operably linked to an open reading frame, the expression of which in an effective amount treats the predetermined cardiac condition.